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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,580	05/22/2000	Frank McKeon	HMSU-P01-048	1156

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FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 02/06/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Application

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Application Number	09/575,580
Filing Date	May 22, 2000
First Named Inventor	Frank McKeon
Art Unit	1653
Examiner Name	Kam, Chih Min
Attorney Docket Number	HMV-048.01

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I am the :

☐ Applicant/Inventor.

☐ Assignee of record of the entire interest.
Certificate under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☒ Attorney or agent of record. Registration Number 46,778

☐ Registered practitioner named in the application transmittal letter in an application without an executed oath or declaration. See 37 CFR 1.33(a)(1). Registration Number _____

Typed or Printed Name: Jennifer K. Holmes

Signature: Jennifer K. Holmes

Date: January 29, 2004 Telephone: 617-832-1770

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 2 forms are submitted.

This collection of information is required by 37 CFR 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Office Action Summary	Application No.	Applicant(s)	
	09/575,580	MCKEON ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1 136(a) In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U S C § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment See 37 CFR 1 704(b)

Status

1)☉ Responsive to communication(s) filed on *02 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☉ Claim(s) *1-3 and 5-13* is/are pending in the application.

4a) Of the above claim(s) *1,3 and 5-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☉ Claim(s) *2 and 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Status of the Claims

1. Claims 1-3 and 5-13 are pending.

Applicants' amendment filed June 2, 2003 (Paper No. 30) is acknowledged. Applicants' response has been fully considered. Claim 2 has been amended, claim 4 has been cancelled in the amendment filed September 9, 2002, and new claim 13 has been added. During a telephone conversation with Attorney on May 15, 2003 (see Interview Summary), Examiner agreed to let applicant elect the method of claims 8-12. Claims 1, 3 and 5-7 are non-elected inventions and remain withdrawn from consideration. Therefore, claims 2 and 8-13 are examined.

Oath/Declaration

2. It is noted that on 5 March 2001 applicant's representative filed a petition under 37 C. F. R. 1.47(a), and the petition has been granted on May 10, 2002 (Paper No. 13).

Election/Restrictions

3. Applicant's election with traverse of Group VI, claims 8-12, drawn to a method for identifying a compound that modulates the activity or level of a Csp protein by contacting a cell with a test compound and determining the level or activity of the Csp protein in Paper No. 30 is acknowledged. The traversal is on the ground(s) that the search including Group VII can be made without additional burden. This is not found persuasive because applicant's response has not demonstrated there is no search burden. Furthermore, coexamination of each of the additional group would have required a search of additional class/subclass. For example, if Group VII were included, it would require additional searches in class 536, subclasses 23.1.

The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not coextensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist. Therefore, coexamination of each of these inventions would require a serious additional burden of search.

The requirement is still deemed proper and is therefore made FINAL.

Rejection Withdrawn

Claim Rejections - 35 USC § 102

4. The previous rejection of claim 2 under 35 U.S.C. 102(e) as being anticipated by Palleja *et al.* (U. S. Patent 5,869,318), is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 4 in Paper No. 30.

Informalities

5. The disclosure remains objected to because the specification cites a nucleic acid having ATCC Deposit No. ____ (e.g., page 27, line 30), however, "ATCC Deposit No." is not provided (see paragraph 4 of the previous Office Action, mailed November 29, 2002).

In response, applicants indicate they will correct the information in the specification and

application. The comment is not persuasive and the objection remains until the information in the specification being corrected.

Claim Objections

6. Claim 8 is objected to because the claim contains recitation of non-elected invention, determining the level of a Csp RNA.

Objection to New Matter Added to Specification

7. The amendment filed June 2, 2003 (Paper No. 30) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The specification does not indicate the nucleic acid sequence that hybridizes under stringent conditions to a nucleotide sequence of SEQ ID NO:2 is at least 70% identical to the nucleotide sequence of SEQ ID NO:2, however, the amended claim 2 recites the new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

Claim 2 is directed to a nucleic acid sequence capable of hybridizing under stringent conditions to SEQ ID NO:2, wherein the nucleic acid sequence is at least 70% identical to the nucleotide sequence of SEQ ID NO:2. The specification indicates a nucleotide sequence which hybridizes under stringent conditions to a nucleic acid shown in SEQ ID NO:2 or complement thereof can be used to isolate nucleic acids corresponding to 5' flanking regions of Csp genes from various animal species (page 32, lines 8-10, 19-20), but it does not indicate the nucleic acid sequence is at least 70% identical to the nucleotide sequence of SEQ ID NO:2. Moreover, the specification does not specify which portion of the nucleotide sequence is at least 70% identical to SEQ ID NO:2. Without guidance on the nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO:2 and is 70% identical to SEQ ID NO:2, one skilled in the art would not know how to identify this nucleic acid. The lack of representative examples and teachings for the nucleotide sequence that hybridizes to SEQ ID NO:2 and having at least 70% sequence identity to SEQ ID NO:2 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

9. Claims 8-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for a method of identifying a compound that modulates the activity or level of a Csp protein, the method comprising contacting a cell comprising a Csp protein with a test compound and determining the level or activity of the Csp

the specification only discloses cursory conclusions without data supporting the findings, which state that in vivo methods can be used to identify compounds that modulate a Csp activity, and the method comprising incubating a cell expressing Csp with a test compound and measuring the Csp mRNA or protein level, where the Csp protein level can be determined by immunoprecipitation or immunohistochemistry using an antibody that specifically recognizes Csp (page 104, lines 6-15). There are no indicia that the present application enables the claims in view of a method of identifying a compound that modulates the activity or level of a Csp protein as discussed in the stated rejection. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the absence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breath of the claims:

The breath of the claims is broad and encompasses unspecified variants regarding the identities of compounds that modulating the activity of Csp protein, and the activity of Csp protein monitored in the presence or absence of compound in the cell, which are not adequately described or demonstrated in the specification.

(2). The absence or presence of working examples:

There are no working examples indicating the claimed methods in association with the variants, the specification has not demonstrated a compound inhibiting or activating the activity

(3). The state of the prior art and relative skill of those in the art:

The prior art (e.g., Barford, TIBS 21, 404 (1996); page 1 of the specification) indicates calcineurin plays a pivotal role in signal transduction, and the present invention relates to the discovery of a family of endogenous inhibitors of calcineurin, named calcipressins, Csp1, Csp2 and Csp3 (page 12, lines 14-18). However, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide teachings on the specific activity of the Csp protein and the identities of the compound that modulating the activity of the Csp to be considered enabling for variants.

(4). Predictability or unpredictability of the art:

The claims encompass a method of identifying a compound that modulates the activity or level of a Csp protein, however, the activity of Csp protein monitored in the cell, and the identities and effects of compounds are not adequately described in the specification, the invention is highly unpredictable regarding the effects of various compounds.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a method of identifying a compound that modulates the activity or level of a Csp protein. The specification indicates Csp activity is intended to encompass any activity of an Csp protein and activities are mediated by Csp, e.g., a binding activity to calcinurin (page 20, lines 4-7), and the term "modulation" refers to both upregulation (i.e., activation or enhancement) and downregulation (i.e., inhibition or suppression; page 24, lines 13-15); it further indicates mouse monoclonal antibodies have been generated primarily

where 3F4A recognizes both Csp1 and Csp2 (page 134, lines 12-20). However, the specification has not demonstrated monitoring the activity or protein level of a Csp protein in the presence of a test compound in the cell, nor has identified a compound that modulating the activity of a Csp protein. Moreover, there are no working examples indicating the effects of the test compounds. Since the specification fails to provide sufficient teachings on the identities of the test compounds, the Csp activity or level being monitored in the cell and the effects of the compounds, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of various compounds in the claimed method.

(6). Nature of the Invention

The scope of the claims encompasses a method of identifying a compound that modulates the activity or level of a Csp protein, but the specification does not demonstrate monitoring the activity or the protein level of a Csp protein, and identifying the compounds as inhibitors or activators in the claimed method. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, the scope of the claim is broad, there is no working examples demonstrating the claimed methods, the teaching in the specification is limited, and the effect of compound is not indicated, and therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of various compounds as modulators for the activity of Csp protein.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

10. Claims 8-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 8-13 are indefinite because of the use of the term "activity of the Csp protein". The term "activity of the Csp protein" renders the claim indefinite it is not clear what activity of the Csp protein is determined, and what the term "Csp" means. A fully spelled out word should be indicated in the first occurrence. Claims 9-13 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D.
Patent Examiner

***

August 15, 2003

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600